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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,025	04/24/2001	Judith Aronhime	1662/52602	6176
26646	7590	05/14/2004	EXAMINER HUANG, EVELYN MEI	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/841,025

**Applicant(s)**

ARONHIME ET AL.

**Examiner**

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 161-166 and 261-279 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 161-166, 263-279 is/are rejected.
- 7) ☒ Claim(s) 261 and 262 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 161-166, 261-279 are pending. Claims 124-160, 167-260 have been canceled according to the amendment filed on 3-31-2003.

#### ***Claim Rejections - 35 USC § 102***

2. The rejection under 35 U.S.C. 102(b) as being anticipated by Benincasa (5891891, PTO-1449) is maintained for claims 165, and claims 273-278.

Applicant submits that the prior art composition does not meet every requirement of the claimed invention wherein the zolpidem hemitartrate has a certain X-ray diffraction pattern.

Benincasa's pharmaceutical composition comprising Zolpidem hemitartrate (column 2, lines 15-25) would be the same as the instant liquid composition comprising a Zolpidem hemitartrate of a particular size, Form D hydrate or solvate in a particular size, since in a solution, the optionally micronized hydrate or solvate crystalline form of the instant zolpidem hemitartrate having a certain X-ray diffraction pattern no longer exist. The prior art composition therefore meet every requirement of the instant composition.

#### ***Claim Rejections - 35 USC § 112(2)***

3. The 112 second paragraph rejection for Claims 161-166, 263-279 is withdrawn upon reconsideration in view of Applicant's remarks.

#### ***Claim Rejections - 35 USC § 112(1)***

4. The written description rejection for Claims 161-166, 263-279 under 35 U.S.C. 112, first paragraph is maintained for reasons of record.

Applicant contends that the statements in the last office action completely ignore the specification which also states: the term zolpidem hemitartrate" includes hydrates and solvates of zolpidem hemitartrate." Specification, page 11, lines 6-7. The hydrate and the solvate

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are contemplated within the term zolpidem hemitartrate and thus, described in the specification to the extent necessary to meet the burden under 112, first paragraph.

On the contrary, the above general statements in the specification is for the generic zolpidem hemitartrate, but is irrelevant to the specific forms of zolpidem hemitartrate, such as form D, which is characterized by certain X-ray diffraction patterns. The specification only discloses a zolpidem hemitartrate *form D having the X-ray powder diffraction pattern having peaks at 7.1, 9.5, 14.1, 19.6 and 24.5 plus or minus 0.2 degrees two-theta*, which is a monohydrate or hemiethanolate (page 18 of the specification). The recited X-ray diffraction pattern is specific for the zolpidem hemitartrate *form D*, and not for the other forms of zolpidem hemitartrate. The zolpidem hemitartrate hydrates (which encompasses any number of water molecules) and solvates (which embraces any solvents) thereof as recited in claims 263, 268 would constitute other forms of zolpidem hemitartrate having different X-ray diffraction patterns from *form D*. Indeed, zolpidem hemitartrate hydrates (which encompasses any number of water molecules) and solvates (which embraces any solvents) having the X-ray powder diffraction pattern having peaks at 7.1, 9.5, 14.1, 19.6 and 24.5 plus or minus 0.2 degrees two-theta as recited in claim 161 are not described in the specification.

#### ***Allowable Subject Matter***

5. Claims 261, 262 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

While Zolpidem hemitartrate in the form of hydrate or solvate is described by Ettema I and II, Form D with the specific X-ray powder diffraction pattern as recited in the instant claims is not taught or suggested by the prior art of record.

***Drawings***

6. New corrected drawings are required in this application. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

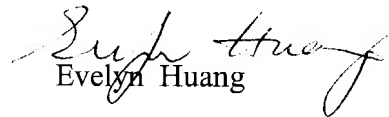
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, appearing to read "Evelyn Huang", is positioned above the printed name.

Evelyn Huang

Primary Examiner

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